

Application No.: 09/700,625

Attorney Docket No.: DALHO1290-1

Filing Date: February 1, 2001

(028614-1102)

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Remarks

The present invention provides compositions containing second or third generation antidepressants, formulated for local or topical administration. Invention compositions have been shown to produce local analgesia in subjects having a site of local discomfort. Invention formulations possess the advantage of providing a higher and more efficacious concentration of active agent to the region of the sensory nerve terminal than is achievable with systemic administration of the same active agent. In addition, invention compositions for local or topical administration greatly reduce the side effects that may result from systemic administration of antidepressants.

Claims 26, 37-44, 49-53 and 72-83 remain pending in the present application. By this response, claims 26, 37, 74, 77, 79 and 82 have been amended to define Applicants' invention with greater particularity. These amendments add no new matter as they are fully supported by the specification and original claims. Applicants respectfully submit that the amendments presented herein place the application in condition for allowance or, at a minimum, reduce the issues for appeal. Accordingly, entry of the amendments is respectfully requested. The present status of all claims in the application is provided in the listing of claims presented herein beginning on page 2.

The rejection of claims 26, 37-43, 49-51, 72-74, 76, 79 and 81 under 35 U.S.C. § 102(b), as allegedly being anticipated by Amer, U.S. Patent No. 5,266,571 (hereinafter referred to as " '571'"), is respectfully traversed. Applicants' invention is based on the discovery that second or third generation antidepressant compositions formulated for local or topical administration are effective local analgesics. '571 only discloses compositions containing serotonin (5-HT<sub>2</sub>) receptor antagonists, which are found therein to be effective in the treatment of hemorrhoids. Applicants respectfully submit that only the present application is directed to second or third generation antidepressant compositions, while '571 is directed to serotonin (5-HT<sub>2</sub>) receptor antagonist compositions. In the case of certain compounds, for example, nefazodone, it appears that a specific compound may fall into both classes of compounds.

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Therefore, in efforts to advance prosecution and reduce the issues for appeal, claims 26, 37, 74, 77, 79 and 82 have been amended herein. Applicants' invention, as defined, for example, by claims 26 and 37 as amended herein, specifically excludes compositions comprising compounds that are serotonin (5-HT<sub>2</sub>) receptor antagonists. Therefore, '571 cannot anticipate the present claims because it does not teach or disclose the specifically claimed compositions of second or third generation antidepressants. Accordingly, reconsideration and withdrawal of this rejection of claims 26, 37-43, 49-51, 72-74, 76, 79 and 81 under 35 U.S.C. § 102(b) are respectfully requested.

The rejection of claims 44, 52, 53, 75, 77, 78, 80, 82 and 83 under 35 U.S.C. § 103(a), as allegedly being unpatentable over '571 in view of Knepp *et al.*, *J. Controlled Release* 12:25-30, 1990 (hereinafter referred to as "Knepp"), is respectfully traversed. As discussed above, Applicants' invention, as defined, for example, by claim 26 as amended herein, specifically excludes compositions comprising compounds that are serotonin (5-HT<sub>2</sub>) receptor antagonists. Claims 44, 52 and 53 are ultimately dependent on amended claim 26. In addition, independent claims 74, 77, 79 and 82 have been similarly amended by the present response. Claim 75 is dependent on amended claim 74; claim 78 is dependent on amended claim 77; claim 80 is dependent on amended claim 79; and claim 83 is dependent on amended claim 82.

The primary reference ('571) only discloses compositions containing serotonin (5-HT<sub>2</sub>) receptor antagonists, which are found therein to be effective in the treatment of hemorrhoids. Thus, '571 does not teach the compositions embraced by the present claims.

Knepp is unable to cure the deficiencies of the primary reference, because Knepp does not teach or suggest the specific claimed compositions of second or third generation antidepressants. In contrast, Knepp merely teaches methods for transdermal drug delivery, without reference to any specific types of drugs or drug classes in particular (using progesterone as a model drug).

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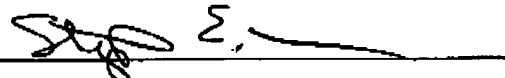
Thus, neither reference, taken individually or in combination, teaches the claimed compositions. Accordingly, reconsideration and withdrawal of this rejection of claims 44, 52, 53, 75, 77, 78, 80, 82 and 83 under 35 U.S.C. § 103(a) are respectfully requested.

Conclusion

In view of the above amendments and remarks, prompt and favorable action on all claims is respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Respectfully submitted,

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Stephen E. Reiter  
Registration No. 31,192  
Telephone: (858) 847-6711  
Facsimile: (858) 792-6773

FOLEY & LARDNER

Customer Number: 30542



30542

PATENT TRADEMARK OFFICE

P.O. Box 80278

San Diego, CA 92138-0278